

The opinion in support of the decision being entered today was not written  
for publication and is not binding precedent of the Board.

## UNITED STATES PATENT AND TRADEMARK OFFICE

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### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Ex parte RAINER H. MULLER

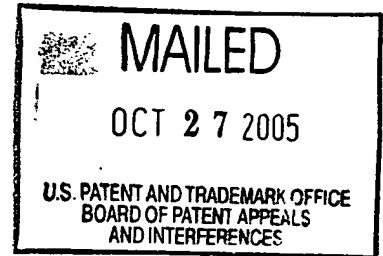
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Appeal No. 2005-1452  
Application No. 09/915,549

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ON BRIEF

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Before GARRIS, WALTZ and JEFFREY T. SMITH, Administrative Patent Judges.  
JEFFREY T. SMITH, Administrative Patent Judge.

### DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-15,  
19-66, 143, 144, 146 and 148-150, all of the pending claims. We have jurisdiction  
under 35 U.S.C. § 134.

### BACKGROUND

The present invention relates to a dispersion which comprises an oily phase, an aqueous phase and at least one active ingredient. The dispersion can be either an oil-in-water emulsion or a water-in-oil emulsion. Representative claim 1 appears below:

1. Dispersion which comprises:  
an oily phase;  
an aqueous phase, in the form of an oil-in-water emulsion or a water-in-oil emulsion; and  
at least one active ingredient that is only slightly or with difficulty soluble in the oily phase and the aqueous phase, wherein the dispersion is free from toxicologically dangerous organic solvents and contains the active ingredient dissolved in a quantity that is greater than the quantity which results additively from its maximum solubility in the oily and the aqueous phase of the emulsion.

The Examiner relies on the following references in rejecting the appealed claims:

Kaufman et al. (Kaufman)	5,616,330	Apr. 01, 1977
Davis et al. (Davis)	EP 0296845	Dec. 28, 1988
(Published European Patent Application)		

Claims 1-15, 19-66, 143, 144, 146 and 148-150 stand rejected under 35 U.S.C. § 103(a) as obvious over Davis. Claims 1-15, 19-66, 143, 144, 146 and 148-150 stand rejected under 35 U.S.C. § 103(a) as obvious over Kaufman.

(Answer, pp. 4-9). We affirm the rejections of claims 1, 12-15, 19-66, 143, 144, 146 and 148-150. However, we reverse the rejections of claims 2-11.

Rather than reiterate the conflicting viewpoints advanced by the Examiner and the Appellant regarding the above-noted rejections, we make reference to the Answer (mailed October 20, 2004) for the Examiner's reasoning in support of the rejections, and to the Brief (filed June 08, 2004) and the Reply Brief (filed December 20, 2004) for the Appellant's arguments there against.

We initially note that Appellant asserts that for purposes of appeal claims 1, 12-15, 19-66, 143, 144, 146 and 148 stand or fall together and claims 149 and 150 stand or fall together. However, claims 2-11 and claims 64-66 do not stand or fall together. (Brief, p. 11). We will direct our comments to claim 1 and address the remaining claims to the extent that they have been argued separately in the Brief.

### OPINION

The Examiner rejected claims 1, 12-15, 19-66, 143, 144, 146 and 148-150 under 35 U.S.C. § 103(a) as unpatentable over Davis alone or Kaufman alone. (Answer, pp. 4-9). We affirm for the reasons presented by the Examiner and add the following for emphasis.

Appellant argues "[a]ccording to the present invention, it is surprisingly possible to enter the supersaturated concentration range without precipitation of drug

crystals during storage. This is achieved by the novel production technology discovered and disclosed in the present application . . . [] Furthermore, at supersaturation levels, the claimed invention is able to provide a dose containing far less carrier than the prior art compositions. Thus, any undesirable effects due to the carrier are substantially reduced in the present invention.” (Brief, pp. 22-23).

These arguments are not persuasive because the subject matter of claim 1 is not limited to the scope of these arguments. The subject matter of claim 1 is directed to a dispersion and not a method of production. Claim 1 also does not specify the storage characteristics of the dispersion and does not set amounts for the carrier component.

Appellant argues “the claimed composition provides supersaturated concentrations of drug, such that the drug crystals do not precipitate out of solution over time. The Examiner does not provide any evidence or convincing argument that one of ordinary skill in the art would now ignore the teachings of Davis and go above the saturation limits of the drug and provide a stable supersaturated drug . . . [] Applicant submits that it is not routine experimentation to ignore teachings of the prior art and use concentrations outside of the disclosed ranges as alleged by the Examiner, especially not supersaturation concentrations that are well-known to be unstable.” (Brief, pp. 23-24).

Appellant's arguments are not persuasive. The dispersion of the claimed invention contains "the active ingredient dissolved in a quantity that is greater than the quantity which results additively from its maximum solubility in the oily and the aqueous phase of the emulsion." It appears that Appellant's arguments regarding supersaturation concentrations refer to the solubility of the active ingredient in the oil or aqueous phases. The claim language requires only a concentration slightly above the maximum solubility in the oily and the aqueous phase of the emulsion. Davis utilizes a surfactant system for dispersing the active ingredient. It is not disputed that the solvation system of Davis allows an active ingredient to be dispersed in an emulsion. Appellant has not argued that the solvation system of Davis does not provide and is not capable of providing an amount of active ingredient contained in the dispersion of Davis is equal to or greater than the amount required to exceed the solubility limits of the active ingredient in the oil or aqueous phases.<sup>1</sup>

Appellant argues, Reply Brief page 5, that the product of Davis is different from the claimed invention. Appellant has not relied on evidence in support of this argument. The active components in the dispersion of Davis are the same as required by the claimed invention. As stated above, Davis utilizes a surfactant system for dispersing the active ingredient. However, Appellant has not established

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<sup>1</sup> Davis discloses that the active ingredient is present at levels that are equal to or exceed its' solubility. Specifically, Davis discloses that during heat sterilisation of amphotericin B a precipitate can result which can be eliminated by removal of the solvent and the addition of an antinucleating agent. (Cols. 7-8).

that the solvation/dispersion system of Davis does not result in a dispersion having the active ingredient in a concentration equal to or greater than the amount required to exceed the solubility limits of the active ingredient in the oil or aqueous phases. See *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657-58 (Fed. Cir. 1990); and *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). Appellant has not directed us to evidence that the product of Davis is substantially different from the claimed product.

Appellant argues that the active ingredient concentrations of Davis are not sufficiently high to obtain acceptable injection volumes. (Brief, p. 25). We do not agree. Davis discloses the active ingredients are present at levels which can be used clinically. (Col. 4, ll. 50-53). Davis also provides examples which show the injection of the dispersion. (Cols. 8-9). Furthermore, Appellant acknowledges, Reply Brief page 9, that the “emulsion according to Davis or Kaufman can be administered to the patient.”

Appellant asserts, Reply Brief page 9, the present invention reduces the amount of emulsion carrier necessary to provide the same drug dose. This argument is not persuasive of patentability because claim 1 is not limited to the same scope. Specifically, the claim does not provide specific amounts for the carrier and drug dosage.

Appellant argues that “the use of ‘comprising’ in claim 1 does not bring back into the claim what is specifically excluded by the claim language. (Brief, p. 26). Appellant’s argument is referring to the exclusion of solvents from the dispersion. We agree that the subject matter excludes solvents from the claimed dispersion. However, Kaufmann (Col. 4, ll. 31-33), like Davis (Col. 3 ll. 38-41), discloses that any solvent used to dissolve the active ingredient should be removed. Thus, the resulting dispersions are free from organic solvents.

Appellant argues that direct comparison based on the percentages of the drugs disclosed by Kaufmann and the present invention is not possible. The Appellant specifically states “[t]he solubility of each drug must be considered.” (Brief, p. 26). However, Appellant then argues that the Kaufmann reference is working at the maximum solubility because of the use of Cholesterol. (Brief, pp. 26-27). This argument is not persuasive because Kaufmann utilizes Cholesterol for stabilizing the emulsion. (Col. 3, ll. 48-60). Appellant has not presented evidence as to the solubility of the taxol with and without Cholesterol in support of this argument. Further, Appellant has not argued that the amount of active ingredient contained in the dispersion of Kaufmann is not dissolved in a quantity that is greater than the quantity which results additively from its maximum solubility in the oily and the aqueous phase of the emulsion.

Claims 64-66 recite that the active ingredient dissolved is greater than the additive quantity by a factor of 2, factor of 5, or a factor of 10. The Examiner has determined that both Davis and Kaufmann disclose forming a dispersion containing an active ingredient. As stated above, the Appellant has not established that the concentration of the dispersed active ingredient is different that the claimed invention.<sup>2</sup>

The Examiner rejected claims 2-11 under 35 U.S.C. § 103(a) as unpatentable over Davis alone or Kaufman alone. (Answer, pp. 4-9). We reverse.

The Davis and Kaufmann references employ a solvent to aid in the dissolving the active ingredient. The Examiner has not identified a disclosure in the references that indicate that the active drug is present in solid crystalline form as recited in claim 2. Thus, the subject matter of claim 2 and claims 3-11, which depend on claim 2, is not obvious over Davis or Kaufmann.

#### CONCLUSION

The rejections of claims 1, 12-15, 19-66, 143, 144, 146 and 148-150 under 35 U.S.C. § 103(a) are affirmed. The rejections of claims 2-11 under 35 U.S.C. § 103(a) are reversed.

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<sup>2</sup> When the USPTO shows sound basis for believing that the invention of the Appellant and the prior art are the same or slightly different, the Appellant has the burden of showing that they are not. See *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); *In re Ludtke*, 441 F.2d 660, 664, 169 USPQ 563, 566 (CCPA 1971).



No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv)(effective Sep. 13, 2004; 69 Fed. Reg. 49960 (Aug. 12, 2004); 1286 Off. Gaz. Pat. Office 21 (Sep. 7, 2004)).

### Affirmed-in-Part

  
JEFFREY T. SMITH  
**Administrative Patent Judge**

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